Attachment 4

ADDS QUESTIONNAIRE

Vendor Name: AscribeRx America, LLC

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1. In what specific patient care settings would this ADD be used? What are the security requirements for the remote location to ensure that medication access is limited only to authorized providers?

Our ADDS machines are well-suited for *Hospitals, Skilled Nursing Facilities, Assisted Living Facilities, Jails, and Multi Doctor Offices*.

Security Requirements:

All ADDS machines are located within a locked room. The facility restricts access to allow only licensed personnel authorized to use the machine to access the room. In addition, the ADDS equipment itself has locked doors and 24/7 video camera surveillance triggered by anyone entering the room. The ADDS electronically tracks and reports all activities associated with the ADDS. All personnel must be authorized users to access the ADDS machine, and are issued unique User IDs and passwords to access the system.

2. How will the pharmacist review medication orders: Is there an interface or other method that allows for prospective review, or is review only retrospective?

With our system, the pharmacist conducts a prospective view. The pharmacy receives electronic or faxed orders. The pharmacy processes the order into the PhIS (Pharmacy Information System) and performs the DUR and formulary check, which is the prospective review. Upon identifying any clinically significant conditions, situations, or items listed above, the Pharmacist will take appropriate steps to avoid or resolve the problem including consultation with the prescribing practitioner. The Pharmacist will document such occurrences. Once the review is complete, the orders are sent to ADDS computer, and the prescription is then ready to be "filled" by the ADDS machine. This allows for the near immediate availability of complete pharmacist reviewed orders rather than a reliance on eKits.

3. What specific features are available through the technology to ensure that the correct medication was removed per the provider's medication order?

Our ADDS equipment has sophisticated technology that assures that the medication dispensed by the machine is the correct medication for the correct patient. The Automated Canister Recognition System (ACRS chip) uses an installed chip to establish a unique identifier for each canister of medication. Each ACRS chip is programmed at the time of canister fill. The system requires a scan of the medication bottle and canister to ensure that the correct drug and strength has been labeled with the correct label for the correct canister.

This allows the canisters to be placed in any open location in the ADDS machine without having to document that location. The ADDS computer receives the resident-specific prescription information from the Pharmacy through an encrypted communications service, and the AscribeRx software identifies the canister electronically and notifies the ADDS machine from where to dispense a particular medication into a sealed patient-specific packet.

4. What are the security features of the technology? How is user access maintained and by whom? Who has the ability to remove medications?

- The Pharmacy PIC, or Pharmacy Personnel monitored by the PIC, will be responsible for all User security access changes. This includes adding and removing Users (resignation), modifying User security rights, and password change requests.
- Each authorized User will be a Nursing Board licensee or authorized licensed pharmacy personnel. Each authorized User ("User" herein) will be assigned a username, password, unique Windows User icon, and Security Rights. The User name and password is unique for each User and will not be reused.
- A policy is in place for the Facility to inform the Pharmacy each time a User leaves the employment of the Facility. This is part of the Facility's off-boarding process.
- Users are required to select their username and enter their password each time they log
 into the ADDS to perform any function in the system including but not limited to
 dispensing oral solid medications and maintaining the canister inventory by adding and
 removing canisters.
- The username created by the computer for use with the ADDS will be a combination of the User's first and last names and can only be modified by changing the User's first and/or last name. Name changes are stored in the database to maintain historical integrity.
- Passwords are stored in a Microsoft SQL Server database using cryptography designed by the National Security Agency (NSA).
- In the event a User is locked out of the ADDS, (3 consecutive unsuccessful attempts) their username will be disabled, denying access to the computer.
- Before a User has access, the user must complete training and demonstrate competency through a Competency check. If automated system reporting finds non-compliance with established policies, the User's access can be suspended until retraining is completed.
- Secured room that is only accessible to Licensed Personnel to restrict access to the system and minimize distractions.

Removal of medications

- An Authorized User will have the ability to remove medication from the ADDS machine via the kiosk interface. This action will create a dispense record and the ADDS will maintain a perpetual inventory of all medications, a complete data trail of the prescriptions that were dispensed at the dose level, as well as the actions of this user.
- All medications removed are supplied in patient-specific packets.

 Physical removal of canisters from the packager must be completed by an authorized User and all canister activity is electronically and video monitored. There is a policy and procedure manual for returning canisters to the pharmacy.

5. How are remote devices restocked? If the medication is transported after being checked by the pharmacist, what features are available that provide for detection of a tampered container?

Every medication is filled into a canister by a Pharmacy Permittee. Then a pharmacist performs the following: verifies the medication in the canister is correct, affixes a canister label, and places a sealed tamper-evident seal on the canister.

The canisters are shipped via a locked tote that is opened by a licensed User at the time of receipt. All activity is tracked by the system and the entire "lifecycle" of the canister is tracked from shipment thru each dispense.

6. Can controlled substances be stocked? If so, what additional security features are available?

Yes, controlled substances can be stocked. All activities are electronically and video monitored to maintain security. The following outlines the policies and procedures for handling controlled substances and dangerous drugs.

Chain of custody

- The sealed canisters are loaded by authorized licensed User by scanning the medication fill label of the canister while logged into the ADDS.
- During the receive canister process, the ADDS records the medication information of the canister, date/time received, and User information of whom the canisters were received by.
- The ADDS has a separate location for controls. There is a separate lock and email notification each time the door is opened that allows for daily auditing of activity.
- The canister is then placed into the controlled substance location of the packager for dispensing by the authorized licensed User.
- As the packager depletes its medication stock, the empty canisters are removed from the packager. If applicable, a replacement canister is placed in the packager by the authorized licensed User.
- The authorized licensed User will complete the return canister process for all canisters that need to be returned to the Pharmacy inventory.
- The pharmacy technician will clean and inspect the canisters prior to re-use.

Discrepancy resolution

- Each canister that contains medication is verified by a Pharmacist prior to dispensing medications into packets from the ADDS.
- If a discrepancy is found, the correct medication will be dispensed from the ADDS using the Re-Dispense function.
- If the system detects a discrepancy in count, at the time of discovery, the pharmacy will

request the activity log of the canister, access logs of the control substance door, and video archive from AscribeRx Technical Support.

- Each dispense, canister movement, and door activity is electronically logged. A complete sequential view of all activity is tracked and video archived.
- The data and video will be provided to the pharmacy and facility to address the discrepancy.

Controlled substance inventory

- The ADDS keeps a perpetual inventory of all medications that are dispensed or distributed from the packager or returned to the Pharmacy inventory, including controlled substances.
- The Pharmacy will conduct an inventory of the canister inventory on the same day as the Pharmacy's annual inventory or as directed by the State Board of Pharmacy.

Controlled substance count sheets

The **Controlled Substance Count Sheet** can be configured to print when the dispensing is complete. The report will print when at least one controlled substance is dispensed. The Controlled Substance Count Sheets must be signed at the time of administration by the nurse, and retained at the LTC, acute or ALF Facility for a period of three years or more depending on state/federal laws and/or regulation requirements.

7. How would patient consultation occur?

Telephone, video conferencing, or written documentation.

- 8. How would the ADDS remote user interact with the pharmacist? What technology options exist? Video, kiosk and phone. A phone and internet camera is located in the ADDS room.
- 9. How would the pharmacist detect drug diversion for medications stocked in the ADDS? What reports are available to allow the pharmacist to monitor safe use of the ADDS technology? Please provide an example of these reports.

The System electronically and video tracks all transactions and interactions with the ADDS. The System provides alerts and reporting to immediately address unauthorized use. Because the system dispenses by day and dose, any diversion would result in routine doses not available to residents and reported missing by nursing, or identified thru the redispense functionality.

Activity reports can be run by a number of parameters including: type (e.g., PRN, routine...) resident, User, or function (dispense, redispense). See attached reports.

10. What specific law changes are recommended to support the use of this remote ADDS technology?

Changes to the law to allow placement of these machines in the locations described in #1 at a minimum, and without advance Board approval of the placement of each ADDS. Regulatory language that allows the Board to add additional locations, not included in Item #1, pursuant to a vote of the Board, rather than through legislation or formal rule-making.

Language that clearly permits pharmacy staff or authorized personnel to load sealed canisters in the machines at these locations. This would include pharmacists, pharmacy staff, nurses, or other personnel designated in writing by the pharmacist-in-charge and who have completed documented training concerning their duties with the ADDS.

New Paradigm In Long Term Care Medication Delivery and Therapy Management

February 2017







LTC Market Change Impacting Pharmacy Services

The primary dispensing modality has not changed in over 30 years!

- Focus on Short-Term Rehabilitation Residents
- Increased Acuity
- Increased Regulations
- High Nurse/Resident ratio (Baby Boomers)
- Increased Weekend and Evening Admits

 Complexity of Medications on the Market (e.g. Ca Channel Blockers)





Process Overview

Order Entry



OnSiteRx® Enabled Pharmacy







Safe & Efficient Administration



Unit Dose Packets



Canister pathway





Drug Canister Details

- The Automatic Canister Recognition System (ACRS chip) uses an installed chip to establish a unique identifier for each canister.
- Allows for canisters to be placed in any open location in the ADDS machine without having to document its location.
- Software identifies the location of each canister electronically and notifies the ADDS machine from where to dispense a particular medication.
- ACRS chip improves safety by eliminating possibility of canister fill and placement errors.

Canister



Each canister is built to specifications. Canister Fill



Canister Recognition Chip





Tamper Evident Seal



Canisters Ready for Shipment





1. Filling Canisters

Filling Procedure

- Place canister on the chip writer.
- Scan the NDC barcode on the medication bottle
- Enter the fill details
 - Qty, Lot #, Exp
- Print and scan the medication fill label.
 - This verifies the information on the label & canister chip match.



Note: The canister is not coded (will not dispense) until all information verified by system



2. Verifying Canister Contents

Pharmacist Procedure

- Verifies the contents of the canister matches the label.
- Adheres label & tamper-evident seal.
- Initials & dates canister label.



Note: Physical Inspection



Canister Label Details

- Unique Canister ID
- Verifying Pharmacist Initials & Date Signed
- Medication Name & Strength
- ✓ NDC
- Schedule
- ✓ Color
- Shape
- Marking
- ✓ Mfr
- ✓ Lot #
- Fill Date
- Exp Date
- ✓ Pharmacist
- Technician
- Pill Qty





3. Canister Delivery

- Canisters are assigned to a facility by scanning. Creating a shipping manifest.
- These canisters are then tracked by the system as "en route".
- Canisters and the shipping manifest are transported by delivery personnel in a sealed tote.





4. Canister Reception Process

Licensed Healthcare Professional Procedure

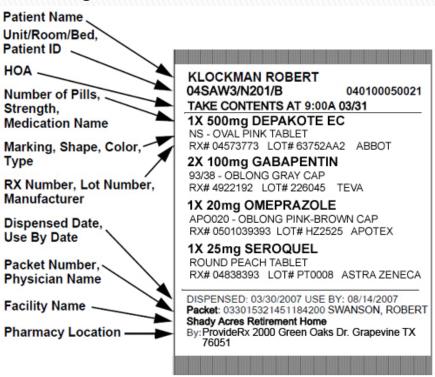
- Signs the canister shipping manifest
- Receives sealed canisters by scanning the medication fill label while logged into the OnSiteRx® Kiosk. (Tracked as delivered)
- Place canister into the secure OnSiteRx®
 Packager or in a secure storage unit adjacent to the Packager until needed.





Medication Packet

- 5 Sigma Accuracy: 23 Times Safer Than Bingo Cards
- Clearly labeled and well-organized
- Capable of printing 19 lines (drug name, bar code, efficacy, patient name, dosage)



Medication description and HOA

- System setup can be tailored to customer requirements
- Font, text size, and number of letters are adjustable
- Line length and position of the text are also adjustable



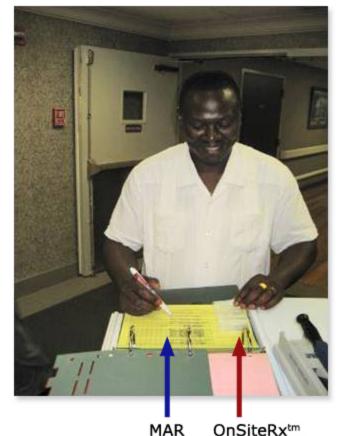
Reverse clear side of Packet



Blister Cards vs. Unit Dose

Accessing 4 separate blister cards and punching out meds vs. tearing open one packet with the same 4 meds.





OnSiteRxtm Packet



Drug Waste using Blister Cards

> 95% eliminated with Multi-dose dispense





Prescription pathways

Order Processing to Medication Administration



Prescription Review & Approval

- Pharmacy receives electronic, or faxed order.
- Pharmacy process order into PhIS.
 - DUR & Formulary Check
- Orders are sent electronically to the facility's OnSiteRx® Kiosk.
 - Order is available within minutes after the pharmacy processes it.



Retrieving Resident Specific Prescriptions

- The OnSiteRx® Kiosk receives resident specific prescription information via an encrypted communication service.
- The licensed healthcare professional request via the OnSiteRx® Kiosk, to retrieve the resident specific order from the OnSiteRx Packager.
- The licensed healthcare professional confirms that the following information is listed on the packet prior to administering the drug: correct resident-patient name, medication, strength, unit, and quantity as directed by the medication administration record.



OnSiteRx® System Software

Overview



OnSiteRx® Software System

Three (3) main components

- OnSiteRx ® Pharmacy System (OPS)
- OnSiteRx® Dispensing System (ods)
- Reporting Center



OnSiteRx ® Pharmacy System (OPS)



Allows pharmacy and support staff to:

- Encode & initialize canister chips
- Manage canister & build information
- Perform formulary management
- Perform user administration
- Perform ODS administration
- Adjust pharmacy preferences



OnSiteRx® Dispensing System

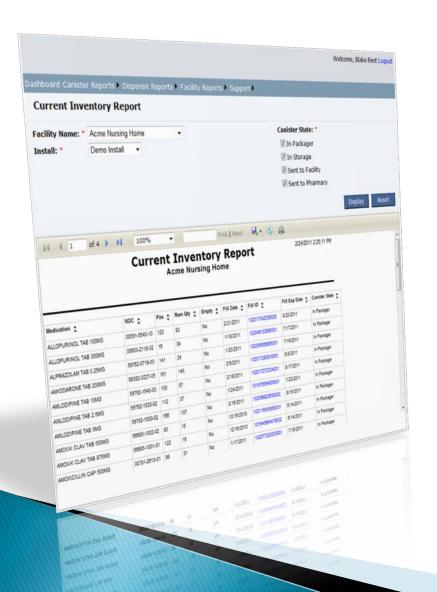


Functionality

- First and stat dose
- On-demand PRN dispensing
- Leave of absence dispensing
- Re-dispense
- Automatic medication reordering
- On-demand routine medications
- Configurable dispensing by:
 - Resident
 - Hall
 - Nursing Station
 - Med Cart



Reporting Center



Reports include but not limited to

- Review Database Records
- Canister Aging
- Canister Replacement
- Controlled Substances Report
- Current Inventory
- Dispenses
- ODS Access Log
- Prescription Information
- Resident Information
- User Information



Hardware

Canisters, OnSiteRx®Packager & Security





General Canister Info

Canister Label



Canister Recognition Chip



Tamper Evident Seal



Each canister is built to specifications. Canister Fill Station





Canisters Ready for Shipment





Canister Management



The OnSiteRx® Pharmacy System keeps detailed information regarding each canister.

- Each canister is assigned a build number and unique canister id upon initialization by our Canister Production team. This information allows us to determine
 - What medications will fit in the canister and prevent loading of unapproved medications
 - Where the canister is currently located
 - What medications it has dispensed in the past
 - Total pill count dispensed.



OnSiteRx® Packager

There are slots for 240 canisters which medication orders are dropped into packets, sealed and printed.







OnSiteRx® Packager Testing & Routine Maintenance



- Each OnSiteRx System
 is put through a 262
 Point Quality Assurance
 Test & Inspection.
- No daily maintenance is required by facility or pharmacy staff.
- Regular QA inspections are scheduled by AscribeRx certified technicians



System Security ALink Now Enhancement

- Full electronic tracking of all activities
- Live and archived video monitoring
- Electronic and manual locking of medication canisters
- Separated locked location for Controls
- Email alerts for all access to Controlled canisters
- Advanced activity reporting







System benefits

Safety, Time, Cost Savings



ADDS Safety Benefits

- Reduced on-hand inventory of medications nurses need to manage
 - Reduction of destruction
 - >Less medications in med cart (including controls)
 - Less opportunity for diversion
- > Full video and electronic tracking
 - Higher accountability
- Packets can be opened at the bedside aiding in medication verification ("5-Rights")
- Less reliance on ekit due to 1st dose from ADDS available (after RPh review) within mins



Nursing Benefits

- First and stat doses available approximately 15 min after sending to Rx.
- Med Pass time significantly reduced.
- Shift change narcotic count time virtually eliminated.
- > Blister pack reordering virtually eliminated.
- > Med cart size reduction in size and weight.
- Entering medication administration information on MAR becomes much more accurate as packet matches MAR.



Resident Benefits

- First and stat dose availability in minutes, not hours.
- ✓ Leave of absence orders organized by day and time of administration.
- Nurses have more time to spend with residents.



Facility Benefits

- Reduction in Med-A and Med-D oral solids waste.
- Consulting pharmacist time to witness medication destruction reduced.
- Significant reduction of nurse administration time managing orders/reorders/missing doses/receiving cards
- Ability to electronically track to the dose level
- Centralize storage of medications (e.g. PRNs)
- Medication accountability and diversion detection.
- Resident plan changes updated immediately.



Doctor, NP and PA Benefits

- ✓ Dramatic reduction in call backs from nurses regarding pharmacy announcing order "not on formulary".
- ✓ Incentivized to use CPOE, prescribing professional can view resident diagnosis and all drugs currently being taken while considering order changes or initiation.



OnSiteRx® System Statistics

Overview



OnSiteRx Remote Dispensing Stats

- > Of the last 4.12Millon meds packaged:
 - > 0.02% system error rate
 - 0.008% canister jams
 - > 88% average improvement in time to 1st dose.
 - > 82.5% average reduction of med waste/returns of oral solids.
 - > 27% average reduction of on site medications for oral solids.



Dispensing Process Accuracy

- Traditional Dispensing Modalities: 8% Error Rate
- OnSiteRx unit: 0.018% Error Rate (n=4.1M)

Monthly average for 10 facilities

Medication Dispensed	145249
Dispense Sessions	4546
Technical Support Calls	46
Technician Dispatched	1
Successful Dispense	99.997%

Equivalent of approximately 4,800 Blister Cards





Username	Prescription	Resident	Quantity Medication	Schedule	Admin Date	HOA	Packet	Туре	Dispensed	Destroy / Redose
"NURSE NAME"	4352736.00	"RESIDENT NAME"	1 GABAPENTIN TAB 600MG		2/6/2017	06:00:00	1703706148-1	Redispense	2/6/2017	Redose
"NURSE NAME"	4418618.00	"RESIDENT NAME"	1 ALPRAZOLAM TAB 0.25MG	4	2/6/2017	00:00:00	1703710255-1	PRN	2/6/2017	
"NURSE NAME"	4382437.00	"RESIDENT NAME"	1 OXYCODONE TAB 5 MG	2	2/6/2017	00:00:00	1703716903-1	PRN	2/6/2017	
"NURSE NAME"	4430683.00	"RESIDENT NAME"	1 LEVOTHYROXIN TAB 25MCG		2/6/2017	08:00:00	1703733522-1	Routine	2/6/2017	
"NURSE NAME"	4430680.00	"RESIDENT NAME"	1 FUROSEMIDE TAB 40MG		2/6/2017	08:00:00	1703733547-1	Routine	2/6/2017	
"NURSE NAME"	4430680.00	"RESIDENT NAME"	1 FUROSEMIDE TAB 40MG		2/6/2017	20:00:00	1703733547-2	Routine	2/6/2017	
"NURSE NAME"	4421021.00	"RESIDENT NAME"	1 OXYCODONE TAB 5 MG	2	2/6/2017	00:00:00	1703733578-1	PRN	2/6/2017	
"NURSE NAME"	4412170.00	"RESIDENT NAME"	1 OXYCODONE TAB 5 MG	2	2/6/2017	00:00:00	1703733626-1	PRN	2/6/2017	

Username	Resident	Prescription No.	Medication	Quantity	State	PRN Schedu	е НОА	Admin Date	Re-Dispensed	Reason
"NURSE NAME"	"RESIDENT NAME"	4431773.00	LEVOTHYROXIN TAB 100MCG	1	L Valid	No	05:30:00	2/8/2017	2017-02-08 05:17:18.	Medication misplaced
"NURSE NAME"	"RESIDENT NAME"	4352736.00	GABAPENTIN TAB 600MG	1	L Valid	No	06:00:00	2/6/2017	2017-02-06 01:42:28.	Quantity dispensed is not accurate
"NURSE NAME"	"RESIDENT NAME"	4427222.00	ATENOLOL TAB 25MG	1	L Valid	No	08:00:00	2/7/2017	2017-02-07 07:34:56.	Quantity dispensed is not accurate
"NURSE NAME"	"RESIDENT NAME"	4352736.00	GABAPENTIN TAB 600MG	1	L Valid	No	06:00:00	2/7/2017	2017-02-07 00:05:44.	Quantity dispensed is not accurate
"NURSE NAME"	"RESIDENT NAME"	4400423.01	GABAPENTIN TAB 600MG	1	L Valid	No	08:00:00	2/8/2017	2017-02-08 05:18:24.	Medication misplaced
"NURSE NAME"	"RESIDENT NAME"	4427222.00	ATENOLOL TAB 25MG	1	L Valid	No	08:00:00	2/8/2017	2017-02-08 08:14:14.	Quantity dispensed is not accurate
"NURSE NAME"	"RESIDENT NAME"	4352736.00	GABAPENTIN TAB 600MG	1	L Valid	No	06:00:00	2/8/2017	2017-02-08 05:15:10.	Quantity dispensed is not accurate

Username	Packet No.	Prescription No.	Resident	Medication	Quantity	Prn	Redispense	Dispense Date	Admin Date
"USER NAME"	1703876563-10	4285102.00	"RESIDENT NAME"	CLOPIDOGREL TAB 75MG	1	No	No	2017-02-07	2/8/2017
"USER NAME"	1703876563-10	4285103.00	"RESIDENT NAME"	METFORMIN TAB 500MG	1	No	No	2017-02-07	2/8/2017